



ANNUAL REPORT
OF THE
BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE
(renamed the Cellular, Tissue and Gene Therapies Advisory Committee)

For the period
October 1, 2003 through September 30, 2004

FUNCTION

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of biological response modifiers which are intended for use in the prevention and treatment of a broad spectrum of human diseases. The Committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Foods and Drugs.

MEMBERSHIP

A roster of members is attached.

MEETINGS

The Committee met two times during the reporting period. Meetings were held in Gaithersburg, Maryland and Silver Spring, Maryland.

The dates of those meetings were October 9-10, 2003 and March 18-19, 2004.

The meetings on October 9-10, 2003 included a closed session to permit discussion of matters of a personal nature.

ACCOMPLISHMENTS

October 9-10, 2003: The topics were allogeneic islet transplantation including Federal oversight of allogeneic islet transplantation, islet processing, islet characterization and quality, possible licensing of islet products, and updates of individual research programs in the Division of Cellular and Gene Therapies and the Division of Therapeutic Proteins. The issues from this meeting are currently under consideration by FDA. On October 10, 2003, the Committee held a closed session to discuss and make recommendations on personnel and program actions for the Laboratory of Immunology and Virology and the Laboratory of Biochemistry. Disclosure of the information discussed during this session would constitute an unwarranted invasion of personal privacy in accordance with 5 U.S.C. 552b(c)(6). The recommendations were utilized by FDA as part of its independent intramural program review.

March 18-19, 2004: The topics included cellular therapies for cardiac disease including cardiomyopathy and ischemic heart disease, autologous myoblast transplantation, bone marrow cell therapy for angiogenesis, hematopoietic and mesenchymal cell therapies, cardiac catheters for delivery of cell suspensions, and transcatheter myocardial cell delivery. These issues are currently under consideration by FDA.

Detailed information related to these meetings is available in the annual report.

9/30/04
Date


Gail Dapolito
Executive Secretary

Biological Response Modifiers Advisory Committee

Chair

Mahendra S. Rao, M.D., Ph.D.

Expertise: Cellular Biology
Term: 05-22-01 - 03-31-05
Chief Stem Cell Biology Section
Laboratory of Neurosciences, 4B17
Gerontology Research Center
National Institute on Aging
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5600 Nathan Shock Drive
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Jonathan S. Allan, D.V.M.

Expertise: Veterinary Medicine
Term: 09-30-02 – 03-31-06
Scientist
Department of Molecular and Experimental
Medicine
Department of Virology and Immunology
Southwest Foundation for Biomedical
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7620 N.W. Loop 410 at Military Drive
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Bruce R. Blazar, M.D.

Expertise: Pediatric Hematology
Term: 05-22-01 – 03-31-05
Professor
Division of Pediatric Bone Marrow
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David M. Harlan, M.D.

Expertise: Transplantation, Autoimmunity
Term: 09-30-02 – 03-31-06
Captain, U.S. Public Health Service and
Chief, Islet and Autoimmunity Branch
National Institute of Diabetes and Digestive
and Kidney Disease, NIH, DHHS
10 Center Drive, Building 10, Room 8N307
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Executive Secretary

Gail Dapolito

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Richard C. Mulligan, Ph.D.

Expertise: Molecular Biology
Term: 05/09/00 - 03/31/04
Mallinckrodt Professor of Genetics
Department of Genetics
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Thomas H. Murray, Ph.D.

Expertise: Bioethics
Term: 01-05-04 - 03-31-07
President
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James J. Mule, Ph.D.

Expertise: Tumor Immunology / TC Clearance
Term: 01-05-04 - 03-31-07
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Translation Science and Technology
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Michael McGillicuddy Endowed Chair
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H. Lee Moffitt Cancer Center and Research
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Expertise: Molecular Biology
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Joanne Kurtzberg, M.D.

Expertise: Pediatric Hematology
Term: 05/09/00 - 03/31/04
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Alison F. Lawton**

Expertise: Industry Representative
Term: 05-22-01 – 03-31-05
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*Consumer Representative

**Industry Representative

Anastasios A. Tsiatis, Ph.D.

Expertise: Biostatistics
Term: 09-30-02 – 03-31-06
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Alice J. Wolfson, J.D.*

Expertise: Women's Health Law
Term: 05/09/00 - 03/31/04
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